DEARTMENT OF HEALTH & HUMAN SERVICES 91695d
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

August 29, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: NYK-2001-116

Mr. Joseph Gurrera
Owner
Citarella Fish Company
2135 Broadway
New York, NY 10023

Dear Mr. Gurrera:

We inspected your seafood processing facility, Lockwood & Winant, Inc., located at 4 & 5 Fulton Fish Market in New York, New York, NY on July 16 through 18, 2001, and found that you have serious deviations from the Seafood HACCP regulations (Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)). These deviations, some of which were previously brought to your attention, cause your scombrotoxin (histamine) forming species of fish (e.g., tuna), vacuum packaged Yellowtail, and refrigerated pasteurized canned crabmeat to be in violation of Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through the links in FDA's home page at www.fda.gov.

The deviations included, but are not limited to, the following:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm did not have HACCP plans for the receipt, display and storage of raw vacuum packaged Yellowtail and refrigerated pasteurized canned crabmeat to control the hazard of Clostridium botulinum toxin formation. Further, the Yellowtail is not labeled as "keep refrigerated" presenting a serious potential for temperature abuse and consumer illness.

2. You must verify that your HACCP plans are adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8 (a). However, your firm does not conduct a HACCP records review for monitoring that occurred at receiving and display of histamine producing fish. This review is required to occur within 1 week of the day that the records are made. Further, your firm has not conducted a reassessment

of your HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually.

3. You must have written product specifications for the fish products you import to assure that these products are not injurious to health or have been processed under insanitary conditions, and affirmative steps assuring that imported products meet your specifications to comply with 21 CFR 123.12 (a). However, your firm fails to meet these requirements for the import of swordfish and tuna.

We may take further action if you do not promptly correct these deviations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter and the inspectional observations (Form FDA 483) issued to and discussed with Leo A. De St. Aubin, HACCP Manager, at the conclusion of the inspection, may not list all the deviations at your facility. You are responsible for ensuring that your seafood processing facility operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Lillian C. Aveta, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issues in this letter, please contact Ms. Aveta at (718) 662-5576.

Sincerely,

Robert L. Hart
Acting District Director

Enclosure: Form FDA 483 dated July 18, 2001